

Complete Summary

GUIDELINE TITLE

Nutrition practice guidelines for type 1 and type 2 diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Nutrition practice guidelines for type 1 and type 2 diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Dec. Various p.

COMPLETE SUMMARY CONTENT

SCOPE
 METHODOLOGY - including Rating Scheme and Cost Analysis
 RECOMMENDATIONS
 EVIDENCE SUPPORTING THE RECOMMENDATIONS
 BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
 QUALIFYING STATEMENTS
 IMPLEMENTATION OF THE GUIDELINE
 INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
 CATEGORIES
 IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Type 1 and type 2 diabetes mellitus

GUIDELINE CATEGORY

Evaluation
 Treatment

CLINICAL SPECIALTY

Endocrinology
 Nutrition

INTENDED USERS

Dietitians

GUIDELINE OBJECTIVE(S)

Overall Objective:

To provide nutrition practice guideline on medical nutrition therapy for individuals with type 1 and type 2 diabetes mellitus

Specific Objectives:

- To define responsibilities within the scope of practice for registered dietitians (RDs) that are carried out in collaboration with other health care providers
- To guide practice decisions that integrate medical, nutritional, and behavioral elements
- To reduce variation in practice among RDs
- To promote self-management education that empowers the patient to take responsibility for day-to-day management and provide the RD with data to make recommendations to adjust nutrition therapy, or recommend other therapies, to achieve clinical outcomes
- To enhance the quality of life for the patient utilizing customized meal planning strategies based on the individual's eating preferences, lifestyle, and goals to improve metabolic control
- To develop standards that can be tested for impact on clinical outcomes
- To define highest quality of care within cost constraints of the current health care environment

TARGET POPULATION

Individuals with type 1 and type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Assessments

1. Medical history, laboratory values, anthropometrics data (height, weight, usual weight, body mass index [BMI])
2. Nutrition-focused assessment:
 - Evaluation of height, weight, usual weight, body mass index, blood pressure, laboratory values, hemoglobin A1c, signs and symptoms.
 - Assessment of client's understanding of diabetes and readiness to learn, identify medications that may affect nutrition therapy, obtain comprehensive medical and food/nutrition history.
 - Assessment of lifestyle factors that would impact meal times.
 - Consideration of co-morbid conditions and need for additional modifications in nutrition care plan.

Management/Medical Nutrition Therapy

1. Intervention and self-management training:
 - Providing meal plan with 3 meals and snacks with consistent carbohydrate appropriate for client's abilities/food preferences/lifestyle/insulin regimen.
 - Providing self-management basics of recording food intake, blood glucose monitoring, ketone testing, food preparation.

- Discussing risks of hyper- and hypoglycemia; review the impact of food and activity on glucose and discuss meal preparations.
 - Mutually establishing goals and outcomes for meal times, physical activity, self-monitoring of blood glucose and record completion.
2. Reassessment and follow-up
 3. Providing documentation to physician and other relevant health care team members

MAJOR OUTCOMES CONSIDERED

- Blood glucose levels (hemoglobin A1c%)
- Insulin sensitivity
- Lipid and lipoprotein levels
- Blood pressure
- Risk for and incidence of cardiovascular disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The priorities for choosing articles to support the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus were:

1. Randomized control trials to evaluate the effect of various factors (macronutrients, weight loss, exercise, self-blood glucose monitoring) on A1c.
2. Consensus Statements from the American Diabetes Association or the American Dietetic Association that are based on the most recent research and practice guidelines and the American Association of Clinical Endocrinologists.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetics Association Health Services Research Task Force. This process is an adaptation of the US Preventive Task Force evidence analysis process.

Rating Scheme

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion (see the "Rating Scheme for the Strength of the Recommendations" field). Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Plus: indicates that the report clearly addresses issues of inclusion/exclusion, bias, generalization and data collection and analysis

Minus: indicates that the above issues are not adequately addressed

Neutral: indicates that the report is neither exceptionally strong nor exceptionally weak

NA: Indicates that report is not a primary reference and therefore the quality has not been assessed

Classes of Research Reports

A. Primary Reports of New Data Collection

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Decision analysis
- Cost-benefit analysis
- Cost-effectiveness study

Class R:

- Review article
- Consensus statement
- Consensus report

Class X:

- Medical Opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Ideal/Goal Values listed in the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus is based on a comprehensive review of published peer-reviewed research and literature. In addition, practice guidelines and recommendations supported by national consensus committees, were also used. In instances where guidelines and recommendations vary among consensus panels, the information was carefully analyzed.

Phase I in the development of the Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus includes the following steps:

Step One: Define the clinical question

Step Two: Conduct a comprehensive search of the literature

Step Three: Gather relevant articles and abstract key information

Step Four: Critique articles and rate the evidence

Step Five: Summarize and integrate results of the review

Step Six: Use the results

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetic Association Health Services Research Tasks Force in December 2000. This process is an adaptation of the United States Preventive Services Task Force

evidence analysis process. ICSI process is designed as a practical approach that is user friendly for the clinician. ICSI classifies research reports as:

1. Primary reports of new data collection
2. Reports that synthesize or reflect upon collections of primary reports

Primary reports are categorized according to the level of evidence with category A (randomized, controlled trials) having the highest level of evidence or showing cause and effect. All other primary reports (cohort studies, case studies, nonrandomized trials with concurrent controls) are only able to show an association--not cause and effect. Reports that synthesize or reflect upon collections of primary reports are meta-analysis, systematic reviews, consensus reports, or medical opinion.

Studies and reports were evaluated individually and categorized according to the class of research report and the quality of the research (positive +, neutral, negative -).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A panel of experts, including practitioners and researchers with a depth of experience in the area of practice, convened as the American Dietetics Associations (ADA) Medical Nutrition Therapy (MNT) Evidence-Based Nutrition Practice Guideline for Type 1 and Type 2 Diabetes Mellitus Writing Group. Their tasks were: first, to agree on a set of recommendations suitable for use in usual clinical situations based on scientific evidence, and where evidence is lacking, on extensive experience and expert opinion; and second, to write the guide (i.e., recommendation) for practice.

Studies and reports within a topic (for example, physical activity) were given a conclusion grade based on the available evidence. Grade I conclusion is supported by good evidence, Grade II by fair evidence, Grade III by limited evidence and Grade IV only by opinion. The Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus Evidence Analysis Workgroup reached a consensus on the conclusion grade for each topic.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion.

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and

consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The American Dietetic Association Medical Nutrition Therapy Evidence-Based Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus has gone through a comprehensive peer-review process for technical accuracy and content and translation to practice, and meets the criteria for level III (gold level) validation as defined by the Quality Management Committee of the American Dietetic Association. At the gold level, recommendations are based on a rigorous prospective effectiveness study.

The Review Panel and Steering Committee included experts in the field (experienced dietetics practitioners, specialists, researchers, and educators) and experts and opinion leaders outside the dietetics profession including a nurse practitioner and physicians. The panel utilized a review form to focus feedback on important elements/criteria. In addition, the protocol was evaluated and reviewed for how reasonable expectations are for reimbursement, a critical element for securing medical nutrition therapy coverage in today's health care market. Previous versions of this guideline have undergone technical accuracy and

translation level I (bronze level) and level II (silver level), usability and acceptance validation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Conclusion grades (I-IV) are defined at the end of the "Major Recommendations" field.

Type 1 Diabetes Mellitus MNT

1. Number of MNT visits

Setting: Ambulatory Care or adapted for other health care settings

Number of Encounters: 4 to 8 (Grade I)

<u>Encounter</u>	<u>Length of contact</u>	<u>Times between encounters</u>
1	60-90 minutes	2-4 weeks
2, 3	30-45 minutes	2-4 weeks
4, 5	30-45 minutes	6-12 months
6, 7, 8	30-45 minutes	As indicated by clinical data and/or changes in medication

2. Clinical Assessment

a. Nutrition/Physical

- BMI: If >25, a 5-10% decrease (Grade II)

3. Therapeutic Lifestyle Changes

Encounter in which behavioral topics are covered may vary according to client's readiness, skills, resources and need for lifestyle changes

a. Food and Meal Planning:

- Adheres to meal plan, exercise and medication treatment plan to achieve blood glucose and lipid goals
- <2400 mg/day sodium
- decrease kcal to prevent weight gain (intensive treatment)
- Carbohydrate: >45% kcal; consistency (Grade I)
- Protein: 15%-20% of daily energy, if renal function normal; 0.8 to 1.0 g/kg with microalbuminuria (Grade II)

- Fat: percentage of kcal from total fat: 25% to 35%, <7 to 10% saturated fats, 10% polyunsaturated fatty acids, <200 to 300 mg cholesterol, limit trans fatty acids (Grade I)
- b. Physical Activity
- 3-4 x per week, 30-60 minutes/day (burn a minimum of 1500 kcal per week) (Grade II)
- c. Self-Monitoring of Blood Glucose
- check blood glucose 4-7 x/day--check more frequently when ill (Grade I)

Type 2 Diabetes Mellitus

1. Number of MNT visits

Setting: Ambulatory Care or adapted for other health care settings

Number of encounters: 4 to 8 (Grade I)

<u>Encounter</u>	<u>Length of contact</u>	<u>Times between encounters</u>
1	60-90 minutes	2-4 weeks
2, 3	30-45 minutes	2-4 weeks
4, 5	30-45 minutes	6-12 months

2. Clinical Assessment

a. Nutrition /Physical

- BMI: If >25, a 5-10% decrease (Grade II)

3. Therapeutic Lifestyle Changes

Encounter in which behavioral topics are covered may vary according to client's readiness, skills, resources and need for lifestyle changes

a. Food and Meal Planning:

- Adheres to meal plan, exercise and medication treatment plan to achieve blood glucose and lipid goals
- <2400 mg/day sodium
- decrease kcal 250-500 of usual intake for gradual weight loss
- Carbohydrate: >45% kcal; consistency (Grade I)
- Protein: 15%-20% of daily energy intake if renal function normal. Limit protein to 0.8-1.0 g/kg with nephropathy (Grade II)
- Fat: percentage of kcal from total fat: 25% to 35%, <7 to 10% saturated fats, 10% polyunsaturated fatty acids, 10-15 % monounsaturated fatty acids, <200 mg cholesterol (Grade I)

b. Physical Activity

- 3-4 x per week, 30-60 minutes/day (burn a minimum of 1500 kcal per week) (Grade II)

c. Self-Monitoring of Blood Glucose

- check blood glucose 4 x/day (Grade IV)

Definitions:

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for Nutrition Practice Guidelines for Type 1 and Type 2 Diabetes Mellitus.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains conclusion statements that are supported by grading worksheets. These worksheets summarize the important studies pertaining to the conclusion. The quality of the evidence supporting key recommendations (i.e., self management, self-monitoring of blood glucose, dietary carbohydrate, dietary protein, physical activity, weight management, prevention and treatment of cardiovascular disease in diabetes, prevention of type 2 diabetes) is graded (positive, negative, neutral) for each study. The type of study is also identified.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Field-testing of the guideline showed that blood glucose control improved when the Nutrition Practice Guidelines (NPGs) were used. The A1C values at 3 months improved in 21 (88%) of the NPG patients compared with 16 (53%) of the usual care patients. The practice guidelines patients achieved a greater reduction in A1C than usual care patients (-1.00 versus -0.33). The registered dietitians (RDs) in the NPG group spent more time with the patients, ~3 visits, compared to ~2 visits in the usual care group.
- Medical nutrition therapy (MNT) using Nutrition Practice Guidelines for both type 1 and type 2 diabetes mellitus resulted in 1% to 2% decreases in A1C (8% to 7%) after 3 to 6 months intervention with an average of 3 counseling sessions with the registered dietitian.
- Self-monitoring of blood glucose is necessary to achieve blood glucose levels as close to normal as possible and to prevent or delay the onset of diabetic complications.
- Some studies have shown short-term improvements in glycemic control by incorporating high-fiber, low glycemic index foods in meals and/or snacks
- Regular physical activity improves insulin sensitivity, enhances weight loss, lowers blood pressure and improves A1C in individuals with type 2 diabetes. Regular physical activity improves cardiovascular fitness and reduces serum lipids and blood pressure in individuals with type 1 diabetes.
- Reduction of energy intake and weight loss independently improve insulin sensitivity in individuals with type 2 diabetes mellitus in the short-term. In addition, weight loss decreases serum lipids, fasting blood glucose, A1C, and abdominal fat in individuals with type 2 diabetes.
- Lifestyle changes including regular physical activity and macronutrient modification (reduced energy, <30% fat, <10% saturated fat) reduced the risk of type 2 diabetes mellitus.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These nutrition practice guidelines are meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This digital media publication is an integral part of the plans for getting the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus to all dietetics practitioners engaged in, teaching about, or researching diabetes as quickly as possible. National implementation workshops at various sites around the country and during the ADA Food & Nutrition Conference & Expo (FNCE) are also planned. Additionally there are recommended dissemination and adoption strategies for local use of the ADA MNT Evidence-Based Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Nutrition practice guidelines for type 1 and type 2 diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Dec. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Dec

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

ADA MNT Evidence-Based Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus Writing Group

Nutrition Practice Guideline for Type 1 and 2 Diabetes Mellitus Evidence Analysis Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Evidence Analysis Workgroup: Karmeen Kulkarni, MS, RD (Chairperson); Marion Franz, MS, RD, LD, CDE; Elvira Johnson, MS, RD, CDE; Carolyn Leontos, MS, RD, CDE; Arlene Monk, MS, RD; Janine Freeman, RD, LD, CDE; Margaret A. Powers, MS, RD, CDE; Linda Snetselaar, PhD, RD; Judith Wylie-Rosett, EdD, RD; Nanna A. Cross, PhD, RD; Ellen Pritchett, RD, CPHQ

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print and CD-ROM copies: Available from the American Dietetic Association, 120 South Riverside Plaza, Suite 2000, Chicago, IL 60606-6995; Phone: (800) 877-1600, ext. 5000; Web site: www.eatright.org; E-mail: sales@eatright.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2003. The information was verified by the guideline developer on August 6, 2003.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

All American Dietetic Association (ADA) Evidence-Based Guides for Practice, Nutrition Practice Guidelines and Protocols will be issued as CD-ROMs. To

purchase a CD-ROM, visit the ADA's online catalog at <http://www.eatright.org/catalog/> or call ADA's Member Service Center at (800) 877-1600, ext. 5000.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004

The logo for FIRSTGOV, with "FIRST" in blue and "GOV" in red, and a small red star above the "I".

